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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,092	04/15/2004	T. Douglas Mast	END5313USNP	7164

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EXAMINER	
TOY, ALEX B	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/825,092	MAST ET AL.	
	Examiner	Art Unit	
	Alex B. Toy	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-13 and 15-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-13 and 15-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 July 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This Office Action is in response to applicant's amendment filed on April 11, 2006. The 35 U.S.C. 112, second paragraph rejection of claim 3 is withdrawn as it is now cancelled. All other prior art rejections with respect to the claims still pending are maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 7, 9-10, 12-15, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Freundlich (U.S. Pat. No. 6,618,620 B1).

Regarding claim 1, Freundlich discloses an ultrasound medical treatment system comprising:

a) an ultrasound medical-treatment transducer 102 (col. 6, ln. 25-30 and Fig. 2); and

b) a controller 106 which controls the medical-treatment transducer to emit ultrasound to thermally ablate patient tissue (col. 3, ln. 9-13), wherein the control includes a control parameter (col. 7, ln. 30-34), and wherein the controller changes the control parameter based on receiving an indication of an occurrence in the patient tissue of a transient, ultrasound-caused, ultrasound-attenuating effect (col. 9, ln. 24-35 and col. 10, ln. 6-58). Since a rise in tissue temperature depends on the absorption of ultrasound (Martin (U.S. Pat. No. 6,007,499) – col. 2, ln. 56-57) and the amount of ultrasound absorption is related to the amount of attenuation (Burdette (U.S. Pat. No. 5,549,638) – col. 5, ln. 37-60), the controller of Freundlich inherently changes the control parameter based on receiving an indication of an occurrence in the patient tissue of a transient, ultrasound-caused, ultrasound-attenuating effect.

Regarding claim 2, Freundlich discloses the ultrasound medical treatment system of claim 1, wherein the control parameter is chosen from the group consisting of an ultrasonic acoustic power density of the ultrasound emitted by the medical-treatment transducer, an ultrasonic frequency of the ultrasound emitted by the medical-treatment transducer, a beam characteristic of the ultrasound emitted by the medical-treatment transducer, a duty cycle of the ultrasound emitted by the medical-treatment transducer, and a pulse sequence of the ultrasound emitted by the medical-treatment transducer (col. 7, ln. 30-34).

Regarding claim 3, Freundlich discloses the ultrasound medical treatment system of claims 1 and 2, wherein the control parameter is a beam characteristic and wherein the beam characteristic is chosen from the group consisting of an active aperture of the

beam, a focusing characteristic of the beam, and a steering angle of the beam (col. 7, ln. 34-38).

Regarding claim 4, Freundlich discloses the ultrasound medical treatment system of claims 1 and 2, wherein the ultrasound-attenuating effect is caused by at least one cause chosen from the group consisting of bubble activity from tissue cavitation, bubble activity from tissue boiling, and a temperature-related change in tissue ultrasonic absorption (col. 9, ln. 24-35 and col. 10, ln. 6-58). In addition, Martin (col. 2, ln. 15-33) and Aida (U.S. Pat. No. 5,485,839 – col. 2, ln. 39-63) disclose that the causes specified in claim 4 are common if not inherent causes of ultrasound attenuation that occur when ablative ultrasound energy is applied to tissue.

Regarding claim 7, see the rejection of claim 4.

Regarding claim 9, Freundlich discloses the ultrasound medical treatment system comprising:

a) an ultrasound medical-treatment transducer 102 (col. 6, ln. 25-30 and Fig. 2); and

b) a controller 106 which controls the medical-treatment transducer 102 to emit ultrasound at a first ultrasound acoustic power density to begin to thermally ablate a tissue ablation depth of an area of patient tissue, wherein the controller reduces the emitted ultrasound to a lower second ultrasound acoustic power density based on receiving an indication of an onset in the patient tissue of a transient, ultrasound-

caused, ultrasound-attenuating effect to complete the thermal ablation of the tissue depth of the area of the patient tissue (col. 10, ln. 24-65).

As claimed, a tissue ablation depth of an area of patient tissue is very broad. With regards to Freundlich, a tissue ablation depth of an area of patient tissue may comprise the entire target tissue mass 104 (Fig. 8). Freundlich further discloses adjusting the thermal dose properties of treatment sites based on the over- or under-ablation of other sites on the same target tissue mass 104 that is at the same tissue ablation depth of an area of patient tissue in order to completely ablate the mass 104 (col. 10, ln. 24-65 and Fig. 8). Therefore, it would have been obvious, if not inherent, for the device of Freundlich to comprise a controller which controls the medical-treatment transducer to emit ultrasound at a first ultrasound acoustic power density to begin to thermally ablate a tissue ablation depth of an area of patient tissue, wherein the controller reduces the emitted ultrasound to a lower second ultrasound acoustic power density based on receiving an indication of an onset in the patient tissue of a transient, ultrasound-caused, ultrasound-attenuating effect to complete the thermal ablation of the tissue depth of the area of the patient tissue. Also see the previous rejection of claim 1.

Regarding claim 10, Freundlich discloses the ultrasound medical treatment system of claim 9, wherein the lower second ultrasound acoustic power density substantially eliminates the ultrasound-attenuating effect. When the controller 106 of Freundlich lowers the power to lower the tissue temperature in response to sensing an excessively high temperature, the lower second ultrasound acoustic power density

inherently substantially eliminates the ultrasound-attenuating effect since the attenuation effect is due to excessively high temperature.

Regarding claim 12, see the rejections of claims 1 and 9.

Regarding claim 13, see the rejections of claims 2 and 12.

Regarding claim 14, see the rejections of claims 3 and 13.

Regarding claim 15, see the rejections of claims 4 and 13.

Regarding claim 18, see the rejections of claims 4 and 12.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5-6, 8, 16-17, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freundlich ('620) in view of Itoh (U.S. Pat. No. 4,757,820).

Regarding claim 5, Freundlich discloses the ultrasound medical treatment system of claims 1, 2, and 4. In addition, Freundlich discloses an ultrasound system, wherein the indication of the occurrence of the ultrasound-attenuating effect is based on magnetic resonance imaging from the patient tissue (col. 10, ln. 24-58 and Fig. 7B). The claim differs from Freundlich in calling for the imaging to be from ultrasound echoing. Itoh, however, teaches an ultrasound medical treatment system, wherein the imaging is from ultrasound echoing (col. 2, ln. 12-20). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the imaging system of Freundlich an ultrasound imaging system in view of the teaching of Itoh as an obvious alternate type of imaging system that is well-known in the art. In addition, on page 6, paragraph 22 of the specification, applicant does not disclose any criticality or unexpected result associated with using an ultrasound imaging system. Furthermore, applicant specifically discloses that MRI is an acceptable alternate imaging system.

Regarding claim 6, Freundlich discloses the ultrasound medical treatment system of claims 1, 2, and 4. Freundlich further discloses the system of claim 5 in view of Itoh. In addition, Itoh discloses a medical-treatment transducer that is an ultrasound medical-imaging-and-treatment transducer, and wherein the imaging ultrasound echo is received by the medical-imaging-and-treatment transducer (col. 2, ln. 12-24).

Regarding claim 8, see the rejection of claim 5.

Regarding claim 16, see the rejections of claims 5 and 15.

Regarding claim 17, see the rejections of claims 6 and 16.

Regarding claim 19, see the rejections of claims 5 and 12.

Claims 11 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freundlich ('620) in view of Ying (U.S. Pat. No. 5,657,760).

Regarding claim 11, Freundlich discloses the ultrasound medical treatment system of claims 9 and 10. Ying teaches monitoring tissue treatment using ultrasound imaging, and it would be obvious to use ultrasound imaging in the system of Freundlich – See the rejection of claim 5.

Freundlich discloses adjusting the ultrasound power in response to physiological tissue parameters such as scatter. Scatter changes the tissue absorption of ultrasound and causes a rise in tissue temperature that inherently indicates ultrasound attenuation (col. 10, ln. 6-10 and the rejection of claim 1). Thus, detecting scatter by a rise in tissue temperature indicates ultrasound attenuation.

Ying discloses that scatter can be caused by air bubbles (col. 14, ln. 28-44). Furthermore, air bubbles arise during ablation and are hyperechoic. Ying teaches using ultrasound to detect this hyperechogenicity (scatter) to monitor ablation progress (col. 14, ln. 52-67).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used ultrasound to detect hyperechogenicity instead of temperature in the system of Freundlich in view of the teaching of Ying as an obvious alternate method that is known in the art for monitoring scatter, an inherent indication of the onset of ultrasound attenuation and a factor affecting ablation progress.

Finally, the site of ultrasound attenuation would inherently be in a region distal to a proximal hyperechoic region because the hyperechoic region of Ying is the site of scatter which leads to the ultrasound attenuation distal from it.

Regarding claim 20, see the rejections of claims 10-12.

Response to Arguments

Applicant's arguments filed April 11, 2006 have been fully considered but they are not persuasive.

Regarding independent claims 9 and 12, applicant argues that Freundlich does not disclose treating an area of tissue at one power level and then treating the same area at a different power level to complete ablation. However, as claimed, a tissue ablation depth of an area of patient tissue is very broad. With regards to Freundlich, a tissue ablation depth of an area of patient tissue may comprise the entire target tissue mass 104 (Fig. 8). See the preceding rejection of claim 9 for further details.

Regarding claims 11 and 20 applicant argues that Freundlich in view of Ying does not disclose that the onset of the ultrasound-attenuating effect is indicated by an inception of a proximal hyperechoic region of the patient tissue with distal ultrasound

attenuation. Specifically, the applicant asserts that Ying is used to predict lesion severity and not monitor ablation progress. On page 4, paragraph 18 of applicant's own specification, however, the applicant defines ablating as creating a lesion in patient tissue. Clearly then, by applicant's own admission, lesion formation and ablation are synonymous. Thus, Ying does teach using ultrasound to detect hyperechogenicity (scatter) to monitor ablation progress.

Reiterating the preceding rejection of claim 11: Ying teaches monitoring tissue treatment using ultrasound imaging, and it would be obvious to use ultrasound imaging in the system of Freundlich – See the rejection of claim 5.

Freundlich discloses adjusting the ultrasound power in response to physiological tissue parameters such as scatter. Scatter changes the tissue absorption of ultrasound and causes a rise in tissue temperature that inherently indicates ultrasound attenuation (col. 10, ln. 6-10 and the rejection of claim 1). Thus, detecting scatter by a rise in tissue temperature indicates ultrasound attenuation.

Ying discloses that scatter can be caused by air bubbles (col. 14, ln. 28-44). Furthermore, air bubbles arise during ablation and are hyperechoic. Ying teaches using ultrasound to detect this hyperechogenicity (scatter) to monitor ablation progress (col. 14, ln. 52-67).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used ultrasound to detect hyperechogenicity instead of temperature in the system of Freundlich in view of the teaching of Ying as an

obvious alternate method that is known in the art for monitoring scatter, an inherent indication of the onset of ultrasound attenuation and a factor affecting ablation progress.

Further, the site of ultrasound attenuation would inherently be in a region distal to a proximal hyperechoic region because the hyperechoic region of Ying is the site of scatter which leads to the ultrasound attenuation distal from it.

Finally, claim 11 contains only functional language and lacks any further structure to support the claim limitations.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AT AT
6/13/06

MICHAEL PEFFLEY
PRIMARY EXAMINER